Claims

1. A method for treating a patient with type 1 diabetes, said method comprising administering to said patient an effective amount of a GLP-1 agonist or a pharmaceutically acceptable salt thereof, where said patient is newly diagnosed with type 1 diabetes when the GLP-1 agonist is first administered to said patient.

2. The method of claim 1, wherein said patient is newly diagnosed with type 1 diabetes before said patient is 18 years of age

3. The method of claim 1, wherein said patient is newly diagnosed with type 1 diabetes before said patient is 16 years of age.

4. The method of claim 1, wherein said patient is newly diagnosed with type 1 diabetes before said patient is 12 years of age.

5. The method of claim 1, wherein said patient is newly diagnosed with type 1 diabetes before said patient is 6 years of age.

6. The method of claim 1, wherein said patient is newly diagnosed with type 1 diabetes while said patient is prepubescent.

7. The method of claim 1, where said patient is further administered insulin.

8. The method of claim 7, wherein said insulin and said GLP-1 agonist or pharmaceutically acceptable salt thereof are administered as a single formulation.

9. The method of claim 8, wherein said single formulation is administered parenterally.

10. The method of claim 1, wherein said GLP-1 agonist or a pharmaceutically acceptable salt thereof is administered parenterally.

11. The method of claim 1, further comprising administering to said patient an autoimmune agent.

12. The method of claim 1, wherein said patient is newly diagnosed with type I diabetes less than 12 months before the first administration of said GLP-1 agonist to said patient.

13. The method of claim 1, wherein said patient is newly diagnosed with type I diabetes less than 6 months before the first administration of said GLP-1 agonist to said patient.

14. The method of claim 1, wherein said patient is newly diagnosed with type I diabetes less than 3 months before the first administration of said GLP-1 agonist to said patient.

15. The method of claim 1, wherein said patient is in remission.

16. The method of claim 15, wherein said remission is defined by the formula: $HbA_{1c} + (4 \times$ the daily insulin dose (U/Kg/24h) $< 9\%$.

17. The method of claim 15, wherein said remission is defined by a C peptide level of greater than 100 pmol/l.

18. The method of claim 1, wherein the GLP-1 agonist to be administered to said patient is GLP-1(7-36)-amide or GLP-1(7-37).

19. The method of claim 1, wherein the GLP-1 agonist to be administered to said patient is an analog of GLP-1(7-36)-amide or GLP-1(7-37).

20. The method of claim 19, wherein said analog is selected from the group consisting of Gly^8-GLP-1(7-36)-amide, Gly^8-GLP-1(7-37), Val^8-GLP-1(7-36)-amide, Val^8-GLP-1(7-37), Val^{8}Asp^{22}-GLP-1(7-36)-amide, Val^{8}Asp^{22}-GLP-1(7-37) , Val^{8}Glu^{22}-GLP-1(7-36)-amide , Val^{8}Glu^{22}-GLP-1(7-37), Val^{8}Lys^{22}-GLP-1(7-36)-amide, Val^{8}Lys^{22}-GLP-1(7-37), Val^{8}Arg^{22}-GLP-1(7-36)-amide, Val^{8}Arg^{22}-GLP-1(7-37), Val^{8}His^{22}-GLP-1(7-36)-amide, and Val^{8}His^{22}-GLP-1(7-37).

21. The method of claim 1, wherein the GLP-1 agonist to be administered to said patient is a derivative of GLP-1(7-36)-amide, GLP-1(7-37), a GLP-1(7-36)-amide analogue or a GLP-1(7-37) analogue.

22. The method of claim 21, wherein said derivative comprises a lipophilic substituent.

23. The method of claim 22, wherein said derivative is Arg^{34}, Lys^{26}(N$^\varepsilon$-(γ-Glu(N$^\alpha$-hexadecanoyl)))-GLP-1(7-37).

24. The method of claim 1, wherein the GLP-1 agonist to be administered to said patient is exendin-4, an exendin-4 analogue or a derivative of said exendin-4 or exendin-4 analogue.

25. The method of claim 24, wherein said GLP-1 agonist is exendin-4.

26. The method of claim 24, wherein said GLP-1 agonist is HGEGTFTSDLSKQMEEEAVRLFIEWLKNGGPSSGAPPSKKKKKK.

27. The method of claim 1, wherein the dosage of GLP-1 agonist to be administered to said patient is from about 0.1 ug/kg/day to about 200 ug/kg/day.

28. The method of claim 27, wherein the dosage of GLP-1 agonist to be administered to said patient is from about 0.5 ug/kg/day to about 20 ug/kg/day.

29. The method of claim 1, wherein the GLP-1 agonist is administered to said patient for at least 4 weeks.

30. A method for predicting whether a patient with type I diabetes will suffer a decrease in beta cell function, said method comprising analyzing a sample from said patient to determine the concentration of endogenous GLP-1 (7-37) and GLP-1 (7-36) amide in said sample, where the greater the concentration of endogenous GLP-1 (7-37) and GLP-1 (7-36) amide in said sample, the greater the risk that said patient will suffer a decrease in beta cell function.

31. The method of claim 30, wherein said sample is selected from the group consisting of serum, plasma and blood.

32. The method of claim 30, wherein said sample is obtained from the patient within 90 minutes after the patient has eaten a meal.

33. The method of claim 30, wherein said sample is obtained from a patient who has been newly diagnosed with diabetes.

34. The method of claim 30, wherein said patient was diagnosed with diabetes less than 12 months before said sample was obtained from said patient.

35. The method of claim 30, wherein said patient was diagnosed with diabetes less than 6 months before said sample was obtained from said patient.

36. The method of claim 30, wherein said patient was diagnosed with diabetes less than 3 months before said sample was obtained from said patient.

37. The method of claim 30, wherein said patient was diagnosed with diabetes less than 2 months before said sample was obtained from said patient.

38. The method of claim 30, wherein said patient was diagnosed with diabetes less than 1 month before said sample was obtained from said patient.

39. The method of claim 30, wherein said endogenous GLP-1 (7-37) and GLP-1 (7-36) amide are measured in a single assay.

40. The method of claim 30, wherein said patient is under 18 years of age.

41. The method of claim 30, wherein said patient is under 16 years of age.

42. The method of claim 30, wherein said patient is under 12 years of age.

43. The method of claim 30, wherein said patient is prepubescent.

44. A method for determining whether to administer a GLP-1 agonist to a patient with type 1 diabetes, said method comprising analyzing a sample from said patient to determine the concentration of endogenous GLP-1 (7-37) and GLP-1 (7-36) amide in said sample, where a concentration of endogenous GLP-1 (7-37) and GLP-1 (7-36) amide of greater than 25 pmol/l in said sample indicates that said patient should be administered a GLP-1 agonist.

45. The method of claim 44, wherein said sample is selected from the group consisting of serum, plasma and blood.

46. The method of claim 44, wherein said sample is obtained from the patient within 90 minutes after the patient has eaten a meal.

47. A method for determining whether to administer a GLP-1 agonist to a patient with type 1 diabetes, said method comprising calculating the sum of said patient's HbA_{1c} level on a given day and four times the patient's daily insulin dose for said day, where

a sum of less than 9% indicates that said patient should be administered a GLP-1 agonist.

48. A method for determining whether to adjust the dose of GLP-1 agonist being administered to a patient with type 1 diabetes, said method comprising:

    a. calculating the sum of said patient's HbA_{1c} and four times the patient's daily insulin dose (U/kg/hour) for a first day;

    b. calculating the sum of said patient's HbA_{1c} and four times the patient's daily insulin dose (U/kg/hour) for a second day; and

    c. comparing the sum obtained in step a) with the sum obtained in step b) where a difference between the sum in step a) and the sum in step b) indicates that the dose of GLP-1 administered to said patient should be adjusted.

49. The method of claim 48, where the second day in step b) is at least four weeks after the first day in step a).

50. The method of claim 48, wherein the dose of GLP-1 agonist administered to said patient should be increased if the sum in step a) is lower than the sum in step b).

51. The method of claim 48, wherein the dose of GLP-1 agonist administered to said patient should be decreased if the sum in step a) is greater than the sum in step b).

52. A method for determining whether a patient with type I diabetes is in remission, said method comprising calculating the sum of said patient's HbA_{1c} level on a given day and four times the patient's daily insulin dose for said day, where a sum of less than 9% indicates that said patient is in remission.

53. The method of claim 52, wherein said patient's HbA_{1c} level is determined at least every four weeks and said calculation is repeated at that time.

54. The method of claim 1, wherein administration of said GLP-1 agonist to said patient is initiated if a sample from said patient is determined to have a concentration of endogenous GLP-1 (7-37) and GLP-1 (7-36) amide of greater than 25 pmol/l.

55. The method of claim 1, wherein administration of said GLP-1 agonist to said patient is initiated if the sum of said patient's HbA_{1c} level on a given day and four times the patient's daily insulin dose for said day is less than 9%.

56. The method of claim 11, wherein the autoimmune agent is glutamic acid decarboxylase (GAD) or a peptide fragment thereof having an epitope for autoantibodies to GAD or that binds to a T cell MHC receptor.

57. The method of claim 56, wherein the autoimmune agent is glutamic acid decarboxylase and the glutamic acid decarboxylase is recombinantly produced.

58. The method of claim 11, wherein the autoimmune agent is an autoantigen associated with autoimmune diabetes or a peptide fragment thereof having an epitope for autoantibodies or that binds to a T cell MHC/HCL receptor.